Attorney Docket No. UAB-15102/22

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BOARD OF APPEALS AND INTERFERENCES

Appellant: Jay M. Meythaler et al.

Serial No.: 10/049,327 Group Art Unit: 1617

Filing Date: May 15, 2002 Examiner: Kathrien Ann Cruz

For: METHOD OF TREATING TRAUMATIC BRAIN AND SPINAL CORD INJURIES AND OTHER NEUROGENIC CONDITIONS USING NON-STEROIDAL ANTI-INFLAMMATORY DRUGS AND NATURALLY OCCURRING CONOTOXINS

APPELLANTS' APPEAL BRIEF UNDER 37 CFR §41.37

Mail Stop Appeal Brief - Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

As required under § 41.37(a), this brief is filed within two months of the Notice of Appeal filed in this case on April 2, 2007, and is in furtherance of said Notice of Appeal.
The fees required under § 41.20(b)(2) are dealt with in the accompanying TRANSMITTAL OF APPEAL BRIEF.
This brief contains items under the following headings as required by 37 C.F.R. § 41.37 and M.P.E.P. § 1205.2:

I.	Real Party In Interest
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I. Real Party in Interest

The real party in interest in this appeal is the Applicant and Assignee, Jay M. Meythaler, M.D., J.D..

II. Related Appeals and Interferences

Appellant is aware of no appeals or interferences pending or otherwise related to the present appeal.

III. Status of the Claims

The present application was initially filed with 35 claims. Claims 36-42 were added by amendment. Claims 2-6, 8-28, 30-33, 37-39, 41, and 42 were canceled. Claims 1, 7, 29, 34-36, and 40 are pending, finally rejected, and under appeal. Claims 1, 29, and 36 are the only pending independent claims.

IV. Status of Amendments Filed Subsequent Final Rejection

No after-final amendments have been filed.

V. Summary of the Claimed Subject Matter

Independent claim 1 is a method for treating a subject having inflammation associated with neurotrauma, the method comprising intrathecally administering by intrathecal catheter to the subject (page 25, lines 5-10) a therapeutically effective amount (page 13, lines 19-22) of choline magnesium trisalicylate (page 15, lines 7-10) or prodrug thereof (page 15, line 10; 19, lines 3-8; page 19, lines 16-18) non-inhibitory of platelets (page 16, lines 13-17) so as to reduce the inflammation associated with the neurotrauma (page 12, lines 15-20; page 25, lines 3-15).

Independent claim 29 is a method for treating a subject having inflammation associated with neuronal injury, the method comprising intrathecally administering by intrathecal catheter to the subject (page 25, lines 5-10) a therapeutically effective amount (page 13, lines 19-22) of choline magnesium trisalicylate (page 15, lines 7-10) or prodrug thereof (page 15, line 10; 19, lines 3-8; page 19, lines 16-18) that is non-inhibitory of platelets (page 16, lines 13-17) so as reduce the inflammation associated with the neuronal injury (page 12, lines 15-20; page 25, lines 3-15).

Independent claim 36 is a method for treating a subject having inflammation associated with neurotrauma, the method comprising intraventricularly administering by intraventricular catheter to the subject (page 14, lines 6-8; page 16, lines 6-10) a therapeutically effective amount (page 13, lines 19-22) of choline magnesium trisalicylate (page 15, lines 7-10) or prodrug thereof (page 15, line 10; 19, lines 3-8; page 19, lines 16-18) non-inhibitory of platelets (page 16, lines 13-17) so as to reduce the inflammation associated with the neurotrauma (page 12, lines 15-20; page 25, lines 3-15).

VI. Grounds of Objection/Rejection to Be Reviewed on Appeal

A. The rejection of claims 1, 29, and 36 under 35 U.S.C. §112, first paragraph, enablement.

B. The rejection of claims 1, 7, 29, 34-36, and 40 under 35 U.S.C. §103(a) over Breitner (US 5,643,960) in view of Bustamante (JPET, 1997; 281:1381-1391) and Grilli (WO 98/20864).

VII. Argument

The Examiner's Position

Examiner's rejections of claims 1, 29, and 36 under 35 U.S.C. §112, first paragraph, as failing to satisfy the enablement requirement is based on the assertion while the specification is "enabling for making and using salts of the claimed compounds, [the specification] does not reasonable (sic) provide enablement for making and using solvates or hydrates of the claimed compounds." (Paper No. 20091109, page 4.) In support of this assertion, Examiner states that: "Finding a solvates (sic) or hydrates (sic) is an empirical exercise." Examiner continues to state that: "Predicting if a certain ester of claimed alcohol, for example, is in fact a solvates (sic) or hydrates (sic), that produces the active compound metabolically, in man, at a therapeutic concentration and a t (sic) a useful rate is filled with experimental uncertainty." (Paper No. 20091109, page 5.) Thus, Examiner asserts that "[i]n order to make all forms of prodrugs would require an extensive amount of experimentation to determine that the active sites of such prodrugs are effective in the treatment of inflammation." (Paper No. 20091109, page 3.) Underlying this assertion is Examiner's finding that there are no working examples of solvates or

hydrates, the unpredictable nature of pharmacokinetics in humans, and a single reference that asserts difficulties in extrapolating between species and a lack of a standard pharmacokinetic protocol. *Id.*, paragraph bridging pages 5-6.

With respect to the rejections of claims 1, 7, 29, 34-36, and 40 under 35 U.S.C. §103(a), Examiner asserts that Breitner teaches "a method of delaying the onset of Alzheimer's disease or related neurodegenerative disorders." (Paper No. 20091109, page 8.) The Breitner method is cited as including "administering to an individual at risk of developing the disease (or disorder) an amount of a nonsteroidal anti-inflammatory agent." *Id.* Breitner is cited as teaching that choline magnesium trisalicylate is a non-steroidal anti-inflammatory agent and that "all of these NSAIDs are potent inhibitors of cyclooxygenase." *Id.*

To support the recognized failure of Breitner to teach administering NSAIDs intrathecally or intraventricularly and administering deacetylated aspirin, Examiner cites Bustamante as teaching intrathecal or intracerebroventricularly administering aspirin and other NSAIDs. (Paper No. 20091109, page 8.) Examiner also cites Grilli as teaching the treatment of Alzheimer's disease using NSAIDs that are sodium salicylate and salicylamide. Examiner cites Grilli as teaching that NSAIDs "can be used in the prevention and/or treatment of glutamate receptor-mediated neuronal damages, independently of any anti-inflammatory properties." *Id.* at 9.)

Motivation to administer NSAIDs intrathecally or intracerebroventricularly is stated to come from the Bustamante teaching such administration. *Id.* at 9.

With respect to the amounts of active agent used, pharmaceutical forms, mode of administration, flavors, and surfactant, Examiner finds these "within the knowledge of the skilled pharmacologist and represent conventional formulations and modes of administration." (Paper No. 20091109, sentence bridging pages 9-10.)

Examiner finds motivation to use deacetylated aspirin in Breitner "because employing any known NSAID, including ASA or of it's (sic) metabolite (i.e., deacetylated aspirin), for the treatment of neuronal damages as taught in Breitner would be reasonably expected to be effective. At least additive effect is expected." (Paper No. 20091109, page 10.)

Appellant's Position

A. The numerous examples of prodrugs in the specification combined with well established knowledge in the art of how to analyze their conversion provides complete enablement for claims 1, 29, and 36.

The specification provides numerous examples of prodrugs, and the level of any required experimentation is routine such that claims 1, 29, and 36 are fully enabled by the specification as filed.

Enablement under 35 U.S.C. §112, first paragraph, is satisfied if a person having ordinary skill in the art can make and use the invention without undue experimentation. "[I]t is well established that enablement requires that the specification teach those in the art to make and use the invention without undue experimentation. Whether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations." *In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988). "Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized by the board in *In re Forman*. 230 U.S.P.Q. 546, 547 (BPAI 1986). They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims." *Id.*

As an initial note, the claims are narrowly drawn to a single composition, choline magnesium trisalicylate (CMT) or a prodrug thereof.

With respect to the guidance provided by the specification, Examiner's first error is the assertion that a prodrug is a solvate or hydrate of a drug. (See Paper No. 20091109, page 5.) Examiner appears unaware that a solvate is merely an aggregate of a solute molecule in an aggregate with a solvent molecule. When the solvent is water, a hydrate is formed. Whether a molecule is in a solution is entirely independent of whether it is a pro-drug. The specification makes clear, and one of ordinary skill in the art understands, that a prodrug is one that is converted into a different form in an organism. This is exemplified by the definition of prodrug in the subject specification at page 19, lines 16-18. For example, esters or amides of CMT are also prodrugs.

In a telling error, Examiner cites page 21 of the specification as the only teaching applicable to prodrugs ignoring the three paragraphs on pages 19-20 when inexplicably asserting that a prodrug must be a solvate or a hydrate. (See Paper No. 20091109, page 5.) In contrast to Examiners erroneous assertion, the specification provides numerous examples of prodrugs. Examples of esters of CMT are taught on page 19, lines 3-8, and this section indicates that typical methods of preparation are known in the art and applicable to CMT. Esters are recognized as prodrugs as exemplified by T. Higuchi and V. Stella, "Pro-drugs as Novel Delivery Systems," Vol. 14 of the A.C.S. Symposium Series, at page 3 of chapter 1, incorporated by reference at page 19, lines 19-21 of the specification. The specification teaches C_1 to C_6 esters with a straight or branched alkyl; C_5 to C_7 cycloalkyl esters, and arylalkyl esters. (page 19, lines 3-7.) Esters are recognized as biotransformable by thioesterases or esterases following administration. Ester prodrugs of dopamine, another neuroactive compound, are art recognized as improving the availability of the active species and as being transformed after absorption. (see T. Higuchi and V. Stella, "Pro-drugs as Novel Delivery Systems," Vol. 14 of the A.C.S. Symposium Series, at pages 10-11 of chapter 1, incorporated by reference at page 19, lines 19-21 of the specification.) The specification also teaches amides of an active compound including amides derived from ammonia, primary C_1-C_6 alkyl amines and secondary C_1-C_6 dialkyl amines wherein the alkyl groups are straight or branched chain, as well as in the case of secondary amines, the amine may also be in the form of a 5- or 6-membered heterocycle containing one nitrogen atom. (page 19, lines 10-13.) These esters and amides represent numerous examples of prodrugs.

One of skill in the art also recognizes that salts or complexes of drugs may also be prodrugs. This is exemplified by the detailed and lengthy examination of prodrugs found in T. Higuchi and V. Stella, "Pro-drugs as Novel Delivery Systems," Vol. 14 of the A.C.S. Symposium Series, page 3 or chapter 1, incorporated by reference at page 19, lines 19-21 of the specification. Examiner admits that the specification is "enabling for making and using salts of the claimed compounds." (Paper No. 20091109, page 4.) Thus, numerous other prodrugs are enabled by the specification.

The specification provides ample guidance on pages 19-20 through two detailed publications illustrating how to modify compounds with biocleavable groups which are

recognized in the art as easily applicable to CMT. These publications are incorporated by reference for this purpose. The subject specification cites T. Higuchi and V. Stella, "Pro-drugs as Novel Delivery Systems," Vol. 14 of the A.C.S. Symposium Series, and "Bioreversible Carriers in Drug Design," ed. Edward B. Roche, American Pharmaceutical Association and Pergamon Press, 1987 for considerations applicable to the synthesis of a prodrug such as of CMT. Higuchi in chapter 1 provides examples of successful modifications of drugs to improve absorption, alter release characteristics, improve aqueous solubility, reduce toxicity, improve patient acceptance, promote patient compliance, improve stability, or reduce formulation problems. As such, a person of ordinary skill in the art has ample guidance as to how to make and use prodrugs of CMT from the specification as filed.

Overall, the specification provides extensive examples of prodrugs of CMT including esters, amides, and salts.

In view of the guidance provided by the specification, combined with well established techniques for determining prodrug conversion, any experimentation, if required, is not undue. The rejection asserts that predicting metabolism from a prodrug to an active species is "filled with experimental uncertainty," and that predicting drug metabolism "is still an experimental science." (Paper No. 20091109, page 5.) The question under 35 U.S.C. §112 is not whether experimental certainty exists, but instead whether any experimentation is undue. The fact that experimentation may be complex does not necessarily make it undue, if the art typically engages in such experimentation. *In re Certain Limited-Charge Cell Culture Microcarriers*, 221 USPQ 1165, 1174 (Int'l Trade Comm"n 1983), aff'd. sub nom., *Massachusetts Institute of Technology v. A.B. Fortia*, 774 F.2d 1104, 227 USPQ 428 (Fed. Cir. 1985). See also *In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988). As an example of the level of experimentation that is not undue, the court in *In re Certain* found that determining the cell culture conditions and cell types suitable for use with culturing surface beads with a charge capacity of less than 0.9 meq/g was not undue experimentation. *In re Certain*, 221 USPQ 1165. In that case a practitioner needed to analyze various buffer conditions, nutrient supplements, atmospheric conditions, culture temperature, and even determine whether the invention would work with any desired cell type. Even with this large array of experimental variables, the experimentation was not held undue because the art typically engages in cell culturing. *Id.*

Should experimentation be required to practice the inventions of claims 1, 29, and 36, it requires fewer experimental variables than those of *In re Certain*, and uses techniques that are customarily practiced. At the time of filing, those of skill in the art routinely and regularly designed modifications to drugs for conversion by the body. Studies in pharmacokinetics, the conversion of a drug by the body, are daily if not hourly events in any pharmaceutical laboratory. These studies require only three steps: 1) make the compound; 2) administer the compound to a subject; and 3) determine parent and metabolite concentrations in the subject as a function of time. A person of ordinary skill in the art recognizes how to dose an organism with a compound, how and when to take biological samples, and how to determine bioavailability from drug concentration typically by mass spectrometry. For example, dosing a compound in an animal is commonly done by intravenous administration, oral administration, or subcutaneous injection. The selection of which route to use is merely based on the goal of the study such as to analyze oral bioavailability, or drug metabolism. Biological samples are routinely taken following drug administration such as obtaining blood from a vein or other technique. Timing is merely a choice of how long to wait after dosing and does not require undue intellectual effort. Finally, determining whether a prodrug is converted "for example by hydrolysis in the blood" (Specification, page 19, lines 18-19) is performed daily typically by liquid chromatography combined with mass spectroscopy. After detection, calculating concentration of parent or metabolites is mere comparision to a standard curve. Overall, any required experimentation is not undue, it is routine.

The outstanding office action cites Wolff, Manfred E. "Burger's Page 6 Medicinal Chemistry, 5ed, Part I", John Wiley & Sons, 1995, pages 975-977 for the proposition that "the lack of any standard pharmacokinetic protocol discussed is particularly relevant." (Paper No. 20091109, page 6.) As is understood in the art, each chemical species requires minor adjustments to the detection protocols. This adjustment occurs daily and is expected by an ordinary practitioner. Thus, individual tweaking of protocols to determine the pharmacokinetics of an administered compound is nothing more than routine.

Finally, the claims are very narrowly drawn to a single compound (CMT) and its prodrugs.

Overall, the specification provides ample guidance in the form of numerous examples of

prodrugs of CMT, volumes of guidance as to how to design prodrugs is provided, assaying for pharmacokinetics is routine in the art, the level of skill in the art is high, and the claims are narrow in scope. The factual considerations reveal that the narrow claims drawn to administering CMT and prodrugs thereof for treatment of neurotrauma or neuronal injury is fully enabled by the specification as filed. As such, the rejections of claims 1, 29, and 36 under 35 U.S.C. §112, first paragraph, must be REVERSED.

B. Correlations to long term prevention of Alzheimer's disease cannot be extended to the active and immediate action needed for treatment of neurotrauma or neuronal injury such that no reasonable expectation of success flows from the cited prior art.

No cited prior art teaches or suggests treatment using CMT. To establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). As explained in greater detail, *ante*, Breitner teaches only prevention. Grilli similarly teaches prevention, but does make the unsupported statement of treatment with aspirin or NaSal. Thus, for a suggestion that CMT will be effective as a therapy, CMT must be an equivalent of aspirin or NaSal. Grilli itself teaches that all NSAIDs are not equivalent with respect to treatment even assuming they are equivalent with respect to prevention. Grilli teaches that indomethacin (another NSAID) was "unable to prevent glutamate-evoked cell death." (page 9, lines 10-13.) As such, there is no teaching of suggestion in the cited prior art alone or in combination of CMT, or a prodrug thereof, for the treatment of neurotrauma or neuronal injury. In the absence of such teaching or suggestion, a *prima facie* case of obviousness is not satisfied.

Further, the cited prior art combination of Breitner in view of Bustamante and Grilli fails to provide any reasonable expectation of success for the treatment of neurotrauma or inflammation associated with neuronal injury with choline magnesium trisalicylate (CMT). The prior art can be modified or combined to reject claims as *prima facie* obvious as long as there is a reasonable expectation of success. *In re Merck & Co., Inc.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). However, evidence showing there was no reasonable expectation of success may support a conclusion of nonobviousness. *In re Rinehart*, 531 F.2d 1048, 189 USPQ 143 (CCPA

1976). A person of ordinary skill in the art has no reasonable expectation of success from the teaching of Breitner alone or in combination with Bustamante and Grilli.

Breitner does not teach treatment of neurotrauma or neuronal injury. The entire underlying purpose of Breitner is to analyze past use of an NSAID and its correlation with subsequent onset of Alzheimer's disease. "The present invention relates, in general, to a method of preventing or delaying the onset of Alzheimer's disease and related neurodegenerative disorders." (Abstract). Nowhere does Breitner teach or suggest any NSAID for therapy, and Examiner fails to find any such teaching.

Breitner associates delayed disease onset with past use. No data, chart, statement, or suggestion in Breitner indicates that the unique properties of CMT such as Ca^{2+} effects and amelioration of remote secondary damage resulting from neurotrauma are necessary or have any role in prevention. Further, one of ordinary skill in the art recognized at the time of filing from animal experiments that treatment of neurotrauma with an NSAID was ineffective. The subject specification teaches: "Up to now, drugs have been used that are only marginally effective in preventing this cascade of events and non-steroidal inflammatory drugs (NSAIDS) (sic) have not been useful in animal models for neurotrauma." (page 8, lines 11-14.) The specification teaches that this may be due to inhibition of platelet function, a process which is not differentiated by or a problem in Breitner, Bustamante, or Grilli.

The claims also require that CMT, or a prodrug thereof, be non-inhibitory of platelets. Platelet activity by NSAIDs occurs by crossover inhibition of both COX-1 and COX-2. Breitner states that COX-2 selective compounds such as naproxen are equally preferred to non-selective compounds such as sulindac. (col. 3, lines 52-61.) Thus, Breitner teaches that selectivity is not necessary. Further, Breitner teaches that aspirin "alone appeared to produce weak but similar effect to NSAIDs" also suggesting that selectivity is not required. (col. 8, lines 54-55.) Aspirin is not useful for the treatment of neurotrauma at least because it will increase bleeding – a wholly undesirable side effect following trauma.

A lack of any reasonable expectation of success for treatment of neurotrauma or neuronal injury with CMT flows directly from the data of Breitner itself. In each case, those taking NSAIDs who had Alzheimer's disease were diagnosed with the same disease as those who did not take an NSAID. As such, a person of ordinary skill in the art reads Breitner as suggesting

that there is no therapeutic benefit to administration of any NSAID, if one had actually been administered after disease onset.

Grilli similarly teaches prevention. Only ASA or NaSal are stated for treatment in Grilli at cited paragraph page 3, lines 11-14. The present claims are not directed to ASA or NaSal. They are directed to CMT and prodrugs thereof. Thus, to find a reasonable expectation of success all NSAIDs must be equivalent such as by having the same mechanism of action. Grilli itself teaches that all NSAIDs are not equivalent with respect to treatment even assuming they are equivalent with respect to prevention. Grilli teaches that indomethacin (another NSAID) was "unable to prevent glutamate-evoked cell death." (page 9, lines 10-13.) Thus, the unsupported statement in Grilli that ASA of NaSal are effective treatments of Alzheimer's disease does not lead one of ordinary skill in the art to other NSAIDs or specifically to CMT for treatment of neurotrauma or neuronal injury. No teaching of Grilli provides any reasonable expectation that CMT will be more like ASA or NaSal than indomethacin.

Bustamante merely teaches intrathecal administration of some NSAIDs. Administration of CMT, the only composition in the present claims, is not even mentioned in Bustamante. As such, Bustamante fails to bolster the deficiencies of Breitner and Grilli.

A person of ordinary skill in the art has no reasonable expectation of success in modifying Breitner to administer CMT or any other NSAID for the treatment of neurotrauma. The mechanisms of treatment and prevention are entirely unique. While eating a low cholesterol diet may prevent a heart attack, eating foods low in cholesterol will not treat myocardial infarction.

In view of the above remarks, the rejections of claims 1, 7, 29, 34-36, and 40 under 35 U.S.C. §103(a) over Breitner in view of Bustamante and Grilli must be REVERSED.

Conclusion

In summary, the specification provides ample guidance such that one of ordinary skill in the art can use CMT and prodrugs thereof for the treatment of neurotrauma or neuronal injury. Further, Examiner's references and combination of references that make up the outstanding rejections fail to establish a *prima facie* case of obviousness by neither teaching nor suggesting treatment using CMT or a prodrug thereof, or providing any reasonable expectation of success

that CMT will be effective if administered for treatment.

Accordingly, the rejections of claims 1, 29, and 36 under 35 U.S.C. §112, first paragraph, enablement, must be REVERSED. Similarly the obviousness rejection under 35 U.S.C. §103(a) with regard to claims 1, 7, 29, 34-36, and 40 must be REVERSED.

VIII. CLAIMS

A copy of the claims involved in the present appeal is attached hereto as Appendix A. As indicated above, the claims in Appendix A include all the amendments filed by Appellant.

The Director is hereby authorized to charge any deficiency in the fees filed, asserted to be filed or which should have been filed herewith (or with any paper hereafter filed in this application by this firm) to our Deposit Account No. 07-1180, under Order No: UAB-15102/22.

Date: May 19, 2010

Respectfully submitted,

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APPENDIX A

CLAIMS ON APPEAL

1. A method for treating a subject having inflammation associated with neurotrauma, said method comprising intrathecally administering by intrathecal catheter to the subject a therapeutically effective amount of choline magnesium trisalicylate or prodrug thereof non-inhibitory of platelets so as to reduce the inflammation associated with the neurotrauma.

2-6. (Canceled)

7. A method according to claim 1, wherein said therapetucially effective amount of choline magnesium trisalicylate further comprises a deacetylated aspirin.

8-28. (Canceled)

29. A method for treating a subject having inflammation associated with neuronal injury, said method comprising intrathecally administering by intrathecal catheter to the subject a therapeutically effective amount of choline magnesium trisalicylate or prodrug thereof that is non-inhibitory of platelets so as reduce the inflammation associated with the neuronal injury.

30-33 (Canceled)

34. A method according to claim 29, wherein therapetucially effective amount of choline magnesium trisalicylate further comprises a deacetylated aspirin.

35. A method according to claim 29, wherein the neuronal injury is caused by Lupus, inflammatory neuropathy, infection, transverse myelitis, Parkinson's disease, CNS vasculitis, or Alzheimer's disease.

36. A method for treating a subject having inflammation associated with neurotrauma, said method comprising intraventricularly administering by intraventricular catheter to the subject a

therapeutically effective amount of choline magnesium trisalicylate or prodrug thereof non-inhibitory of platelets so as to reduce the inflammation associated with the neurotrauma.

37-39 (Canceled).

40. A method according to claim 36, wherein therapetucially effective amount of choline magnesium trisalicylate further comprises a deacetylated aspirin.

41-42. (Canceled).

APPENDIX B

EVIDENCE

There is no evidence that has been entered or relied upon in this appeal.

APPENDIX C
RELATED PROCEEDINGS

There are no decisions that have been rendered by a court or the Board in any proceeding identified in the related appeal.